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Philips Medical Systems (Cleveland) Inc.

510(k) Summary

Brilliance iCT

510(k) Number K131773

Applicant's Name:

Philips Medical Systems (Cleveland), Inc.
595 Miner Road
Cleveland, Ohio 44143

SEP 2 4 2013

Contact Person:

Catherine M. Connell
Regulatory Affairs Specialist
Philips Medical Systems (Cleveland), Inc.
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Trade Name:

Brilliance iCT

Preparation Date:

July 09, 2013

Classification:

Name: System, X-Ray, Tomography, Computed
Product Code: JAK
Regulation No: 21 CFR 892.1750
Class: II
Panel: Radiology

Device Description:

The Brilliance iCT is a Whole Body Computed Tomography (CT) X-Ray System featuring a continuously rotating x-ray tube and detectors gantry and multi-slice capability. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the body taken at different angles and planes. This device also includes signal analysis and display equipment; patient and equipment supports; components; and accessories.

Intended Use Statement:

The Brilliance iCT is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment; patient and equipment supports; components; and accessories.

Predicate Device:

Substantial equivalence to the following predicate device is claimed:

Device Name	510(k) No.	Date of Clearance
Brilliance Volume	K060937	June 5, 2006

Compliance with Standards:

Brilliance iCT complies with the following standards:

- AAMI / ANSI ES 60601-1:2005/C1:2009 (R)2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2007 (Ed. 3), Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-3:2008 (Ed. 2), Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
- IEC 60601-2-44:2009 (Ed. 3), Medical electrical equipment. Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography.
- IEC 61223-3-5:2004 (Ed. 1), Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment.

The system complies with performance standards for Computed Tomography (CT) Equipment and Laser products (21 CFR 1020.33 and 21 CFR 1040.10, respectively).

Technical characteristics in comparison to predicate:

Both the cleared Brilliance iCT and its predicate device consist of:

- Operator station
- Gantry
- Patient table
- Patient supports (positioning aids)

The difference between the modified Brilliance iCT and its previously cleared predicate is:

- Modified detection array that maintains the same structure of 672 x 128 detectors

Substantial Equivalence:

The modified Brilliance iCT is a modification of its predicate device, the "Brilliance Volume". Both are Whole Body Computed Tomography (CT) X-Ray Systems, featuring a continuously rotating x-ray tube and detectors gantry and multi-slice capability, to reconstruct cross-sectional images from the acquired x-ray transmission data.

The modified Brilliance iCT and the legally marketed Brilliance iCT have the same intended use and use the same technology as the predicate device. The modifications that were made are to the detection array and in the supporting software.

The safe and effective performance of the modified Brilliance iCT has been clearly demonstrated by bench tests.

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Performance Data:

The following tests demonstrated that the modified Brilliance iCT system continues to conform to IEC 61223-3-5:2004:

- CT Number, Uniformity, Noise and Tomographic Section Thickness Measurements
- CTDI Dose Measurements
- Air Dose Measurements
- Spatial Resolution Measurements
- Low Contrast Detectability Measurements

Clinical evaluation demonstrated that images, which are reconstructed by the modified system, have been evaluated by a radiologist as being of diagnostic quality.

Conclusion:

Philips Medical Systems (Cleveland), Inc. believes that, based on the information provided in this submission, the modified Brilliance iCT is substantially equivalent to its predicate device without raising any new safety and/or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 24, 2013

Philips Medical Systems (Cleveland) Inc.
% Ms. Catherine M. Connell
Regulatory Affairs Specialist
595 Miner Road
CLEVELAND OH 44143

Re: K131773
Trade/Device Name: Brilliance iCT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: August 22, 2013
Received: August 27, 2013

Dear Ms. Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

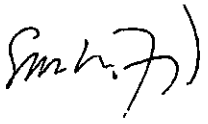
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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Philips Medical Systems (Cleveland) Inc.

510(k) Number (if known): K 131773

Device Name: Brilliance iCT

Indications for Use:

The "Brilliance iCT" is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, components, and accessories.

Prescription Use ____X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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